



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

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|--------------------------------|---|--------------------------------|
| Summary for ARTG Entry: | 153257 | Orthoplex Joint Tissue Support |
| ARTG entry for | Medicine Listed | |
| Sponsor | Bio Concepts Pty Ltd | |
| Postal Address | PO Box 190, Banyo, Brisbane, QLD, 4014 Australia | |
| ARTG Start Date | 24/06/2008 | |
| Product Category | Medicine | |
| Status | Active | |
| Approval Area | Listed Medicines | |

Conditions

Colouring agents used in listed medicine for ingestion, other than those listed for export only under section 25 of the Act, shall be only those included in the list of 'Colourings permitted in medicines for oral use'.

The sponsor shall keep records relating to this listed medicine as are necessary to: (a) Expedite recall if necessary of any batch of the listed medicine, (b) Identify the manufacturer(s) of each batch of the listed medicine. Where any part of or step in manufacture in Australia of the listed medicine is sub-contracted to a third party who is not the sponsor, copies of relevant Good Manufacturing Practice agreements relation to such manufacture shall be kept.

The sponsor shall retain records of the distribution of the listed medicine for a period of five years and shall provide the records or copies of the records to the Complementary Medicines Branch, Therapeutic Goods Administration, upon request.

Where a listed medicine is distributed overseas as well as in Australia, product recall or any other regulatory action taken in relation to the medicine outside Australia which has or may have relevance to the quality, safety or efficacy of the goods distributed in Australia, must be notified to the National Manager Therapeutic Goods Administration, immediately the action or information is known to the sponsor.

Products

1 . Orthoplex Joint Tissue Support

| | | | |
|---------------------|-------------------------|-----------------------|------------|
| Product Type | Single Medicine Product | Effective Date | 27/11/2020 |
|---------------------|-------------------------|-----------------------|------------|

Permitted Indications

Antioxidant/Reduce free radicals formed in the body
Helps reduce/decrease free radical damage to body cells
Maintain/support collagen formation
Maintain/support natural liver cleansing/detoxification processes
Maintain/support energy production
Maintain/support eye health
Maintain/support general health and wellbeing
Maintain/support healthy teeth
Maintain/support connective tissue health
Aid/assist/helps connective tissue production/formation
Maintain/support bone health
Helps maintain/support joint cartilage health
Maintain/support cardiovascular system health
Maintain/support healthy cardiovascular system function
Maintain/support blood capillary health
Maintain/support healthy thyroid gland function
Maintain/support healthy thyroid hormones
Aid/assist thyroid hormone production
Maintain/support smell sensation
Maintain/support taste sensation
Maintain/support bile production
Maintain/support immune system health
Maintain/support healthy immune system function
Maintain/support healthy immune system function
Maintain/support immune system to fight illness
Aid/assist/helps protein synthesis in the body
Maintain/support absorption of dietary (state vitamin/mineral/nutrient)

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Maintain/support (state vitamin/mineral/nutrient) levels in the body
Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)
Support healthy stress response in the body
Aid/assist/helps synthesis of neurotransmitters
Maintain/support nervous system health
Maintain/support nervous system function
Maintain/support skin health
Maintain/support skin integrity/structure
Maintain/support wound healing in healthy individuals
Maintain/support skin repair/healing/regeneration in healthy individuals

Indication Requirements

Product presentation must not imply or refer to vision correction, faults or serious eye disease e.g. macular degeneration.
Product presentation must not imply or refer to any thyroid related diseases.
Product presentation must not imply or refer to serious immunological diseases.
Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).
Product presentation must not imply or refer to mental illnesses, disorders or conditions.
Product presentation must only refer to detoxification in relation to natural body processes.
Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis.
Note: this requirement is not intended to apply where the indications referring to osteoporosis specified in column 2 of Table 2 of this instrument are also used.
Product presentation must not imply or refer to any form of arthritis or osteoarthritis unless qualified as mild.
Product presentation must not imply or refer to serious cardiovascular conditions.
Product presentation must not imply or refer to drugs/alcohol.
If product is indicated for weight loss, label statement: When used in conjunction with a program of reduced intake of dietary calories and increased physical activity.
If product is indicated for supplementation, Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).
Product presentation must not imply or refer to circulatory disorders/diseases/conditions e.g. thrombosis.
Label statement: If symptoms persist, talk to your health professional.
Product presentation must not imply or refer to disease in any body organ, in particular the kidney or liver.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

This medicine contains selenium which is toxic in high doses. A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.
Contains Fish/fish products.
Seek professional advice before long term use.
Vitamins can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin supplements should not replace a balanced diet.
If symptoms persist consult your healthcare practitioner (or words to that effect).
Contains potassium. If you have kidney disease or are taking heart or blood pressure medicines, consult your doctor or pharmacist before use. Keep out of reach of children.

Additional Product information

Pack Size/Poison information

| Pack Size | Poison Schedule |
|-----------|-----------------|
|-----------|-----------------|

Components

1 . Formulation 1

| | |
|-------------------------|--------------|
| Dosage Form | Powder, oral |
| Route of Administration | Oral |



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Visual Identification

Active Ingredients

| | |
|---|--------------------------|
| ascorbic acid | 83.33 mg/g |
| borax | 2.7 mg/g |
| Equivalent: boron | .31 mg/g |
| bovine sodium chondroitin sulfate | 16.67 mg/g |
| Equivalent: chondroitin sulfate | 15 mg/g |
| calcium pantothenate | 5 mg/g |
| Equivalent: pantothenic acid | 4.58 mg/g |
| Citrus bioflavonoids extract | 55 mg/g |
| copper gluconate | 641 microgram/g |
| Equivalent: copper | 83.33 microgram/g |
| creatine monohydrate | 83.33 mg/g |
| glucosamine hydrochloride | 83.33 mg/g |
| Equivalent: glucosamine | 69.17 mg/g |
| glucosamine sulfate potassium chloride | 83.33 mg/g |
| Equivalent: glucosamine | 49.26 mg/g |
| Equivalent: potassium chloride | 20.52 mg/g |
| glycine | 243.5 mg/g |
| leucine | 33.33 mg/g |
| lysine hydrochloride | 100 mg/g |
| selenomethionine | 18.13 microgram/g |
| Equivalent: selenium | 7.25 microgram/g |
| valine | 33.33 mg/g |
| zinc amino acid chelate | 4.17 mg/g |
| Equivalent: zinc | .834 mg/g |

Other Ingredients (Excipients)

ascorbyl palmitate
betacarotene
citric acid
colloidal anhydrous silica
Flavour
Gelatin
malic acid
mixed (low-alpha type) tocopherols concentrate
potable water
silicon dioxide
Soya Oil
Stevia rebaudiana
sucrose
tapioca starch

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